Consumer Stakeholder Meeting
HHS Importation Task Force
Friday, March 19, 2004
Food and Drug Administration, Rockville, MD
Statement of Frances B. Smith, executive director, Consumer Alert

Good morning. I am Frances Smith, executive director of Consumer Alert. Our consumer group often looks at the law of unintended consequences, that is, public policies that may be intended to help consumers often have negative effects instead.

In the case of importation and reimportation of pharmaceutical drugs, the balance between the interests of the current generation and those of the future needs to be considered. This is not to say that the high cost of drugs for those in financial need is not a problem in need of fixing. But we must ask ourselves – is the "cure," drug reimportation, worse than the "disease," high drug prices? Reimportation is not a sustainable solution – it presents serious risks to current and future generations. Cheap prices for drugs today through reimportation can be very costly tomorrow.

Drug prices in other countries may be below some US prices because they are subsidized by foreign taxpayers' money, or the national governments may simply demand that companies lower the prices by instituting price controls. While pharmaceutical companies will only do business in those countries if it is economically sensible for them to do so, that is, they will make at least some profit, mandatory price controls lower the benefits companies will receive for their development. The result can be less interest and less investment in research and development.

Drug reimportation and other proposals to restrict prices of medications would erode the foundations of new drug development. With the average cost of bringing a new drug to market at a staggering $800 million,[1] and requiring 10 to 12 years to reach that stage, what will be the financial incentive for companies to invest in new drugs? Many EU countries, formerly leaders in pharmaceutical R&D, are losing [2]

Importing a country's price controls also carries significant risks for consumers. In many countries where prescription drug prices are set, those policies are part of their national health care systems – systems that often impose other controls, such as rationing of health care services. Often, new drugs are often not available in the formularies, and thus

---

[1] Tufts Center for the Study of Drug Development press release, May 13, 2003, http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29

[2] Economic and Social Research Council, Press Release on ESRC research study, 22 March 2004, "UK industry is the loser from parallel trade in pharmaceuticals," which includes the following quote: "The shipment of bona fide pharmaceutical drugs into Britain from Europe may cost the UK pharmaceutical industry more than £770million a year. The net effect on the UK economy as a whole, taking into account the benefit to consumers of lower pharmaceutical prices, may be more than £290million. In addition it may undermine the long-term viability of R&D on pharmaceuticals, at a time when the Government is trying to promote basic scientific research." Study was not released until after the Consumer Stakeholder meeting.

patients don't have access to what may be superior treatments or, in some cases of rare diseases, any treatment at all.

New life-saving drugs are often very expensive. However, for some diseases, alternative treatments, if available at all, often have even bigger price-tags. For example, a new breakthrough drug available to treat chronic myeloid leukemia might cost around $2200 a month; among the few alternatives available is a bone marrow transplant that can cost around $200,000 – and only if suitable donors can be found.[3]

In relation to the costs of bringing new drugs to market, Consumer Alert would like to commend the FDA for its study, *Innovation or Stagnation? Challenge and Opportunity on the Critical Path to New Medical Products.*[4] As part of its analysis, we would urge the FDA to identify significant roadblocks in the drug approval process that may unnecessarily raise the costs of drug development and stand in the way of new treatments for diseases.

For people who cannot afford their needed medications, there are now some private actions they can take to reduce the costs of their drugs - shopping around for the best price, for example. The "Rx Challenge" surveys, sponsored in May 2003 by three non-profit groups, compared retail prices charged for seven commonly prescribed drugs in the same towns. The sample of pharmacies ranged from independently owned business to large retail and discount chains and two internet providers. In every city and state surveyed, the results show a wide variance in prices for the same drug. In Virginia, for example, consumers could save from between 29 percent to a whopping 559 percent by comparison shopping.

Lower-income consumers can also take advantage of some pharmaceutical companies' discount card programs, and other means. The new Medicare discount card program can also help the needy.

In summary, Consumer Alert would offer that there are no easy answers to the issue of the cost of prescription drugs in relation to importation and reimportation issues, and easy "solutions" may have significant negative effects. We thus recommend that the Task Force, in its review of the importation and reimportation issues, undertake a research and consumer education program to assess the following critical issues:

- ?? What are some of the longer-term effects of reimportation on consumers and their access to new drugs? Research projects
- ?? What is the experience in other developed countries that have price-controls on prescription drugs – rationing, lack of access to new therapies? Research projects
- ?? For some life-threatening diseases, how does the cost of medication compare with the cost and/or the risks of other alternatives, e.g., operations, transplants, etc.? Research projects

[3] Vasella, Daniel and Slater, Robert, *Magic Cancer Bullet*, Harper 2003.
[4] http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf

?? How can lower-income consumers currently through private programs and under the new Medicare benefits significantly reduce their prescription drug costs? Consumer education programs
?? Are there unnecessary roadblocks in the FDA drug approval process that add significant costs to the development of new drugs? Research re FDA program "Innovation or Stagnation?"